

REMARKS

I. INTRODUCTION

Claim 1 has been amended merely to remove a minor informality and not for any reason relating to patentability thereof. New claims 68 and 69 have been added, as provided in the claim listing above. Accordingly, claims 1, 2, and 56-69 are now under consideration in the present application. It is respectfully submitted that no new matter has been added.

II. REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN

Claim 60 stands finally rejected under 35 U.S.C. § 112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner alleges that it is not clear how the acute angle is defined relative to the surface as the wire is essentially circular and presents multiple angles.

Applicants respectfully assert that claim 60 is in no way indefinite as asserted in the Final Office Action. As stated in paragraph [0037] of the present specification, for example, “[o]ther deformations in the wire suitable to grasp the chord 10, such as sharp to orthogonal bends or V-shapes, are possible.” (*Specification*, paragraph [0037]). Accordingly, Applicants respectfully submit that the rejection to claim 60 under 35 U.S.C. § 112, second paragraph should be withdrawn.

IV. REJECTIONS UNDER 35 U.S.C. §§102 and 103 SHOULD BE WITHDRAWN

Claims 1, 2, 56 and 57 stand finally rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,643,248 issued to Yoon (the “Yoon Patent”). Claims 1, 58, 59, 62 and 63 stand finally rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,957,863 issued to Koblish et al. (the “Koblish Patent”). Claim 61 stands finally rejected under 35 U.S.C. § 103(a) as allegedly

being unpatentable over the Koblish Patent. Claims 64 to 66 stand finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Yoon Patent, and further in view of U.S. Patent No. 6,626,899 issued to Houser et al. (the “Houser Patent”). Claim 67 stands finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Yoon Patent, and further in view of U.S. Patent Application Publication No. US 2002/0173811 to Tu et al. (the “Tu Publication”).

Applicants respectfully assert that (i) the Yoon Patent fails to teach, suggest or disclose the subject matter recited in independent claim 1 and the claims which depend therefrom, (ii) the Koblish Patent fails to teach, suggest or disclose the subject matter recited in independent claim 1 and the claims which depend therefrom, and (iii) the Houser Patent and the Tu Publication fail to cure the deficiencies of the Yoon Patent and the Koblish Patent to teach or suggest the subject matter recited in independent claim 1 and the claims which depend therefrom.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; *also see Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

Under 35 U.S.C. § 103(a), a person is not entitled to a patent even though the invention is not identically disclosed or described as set forth in §102, “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law,

whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the “TSM test”). See *In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit’s application of the TSM test, see *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; see *In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, “the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure.” *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O’Farrell*, 853 F.2d. 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant’s disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent

teachings of a prior art reference may be considered under a Section 103 analysis. See *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

The Yoon Patent “relates to medical procedures and instruments and, more particularly, to a medical instrument that prevents probes from applying excessive force to anatomical tissue structures by retracting or protruding the probes” (see the *Yoon Patent*, col. 1, lines 8-12).

The Koblish Patent describes “[a] deflectable biopsy catheter for obtaining a tissue sample from a body cavity of a patient comprising . . . a pair of biopsy jaws coupled to the distal end of the catheter shaft and having first and second opposed free cutting surfaces exposable for contact with a selected area of tissue within the patient's body cavity and movable with respect to each other to cut a tissue sample from the selected area of tissue” (see the *Koblish Patent*, Abstract).

Independent claim 1 recites an apparatus for treating atrioventricular valve regurgitation which includes, *inter alia*, **a cutting arrangement** configured to sever at least one chord attaching an atrioventricular leaflet to a internal cardiac muscle **and a grasping arrangement** configured to constrain the movement of a chord relative to the catheter. In particular, Applicants respectfully submit that neither the Yoon Patent nor the Koblish Patent disclose both a cutting arrangement and a grasping arrangement, i.e. two separate arrangements. Rather, the Yoon Patent describes a hook, which the Examiner admittedly asserts on page 3 “serves as both a grasping and cutting means” (see *Final Office Action*, p. 3, lines 6-7), and the Koblish Patent describes jaws that work together to form a cutting member, which the Examiner asserts on page 3 inherently grasp and cut a biopsy sample and operate via a wire looped into the jaws, making the wire a part of the grasping member

(see *Final Office Action*, page 3, lines 13-16). Moreover, the hook described in the Yoon Patent and the jaws described in the Koblish Patent each serving as both a cutting arrangement and a grasping arrangement preclude the ability to separately maneuver and adjust each of the two arrangements. As neither the Yoon Patent nor the Koblish Patent disclose both a cutting arrangement and a grasping arrangement as two separate arrangements, as explicitly recited in independent claim 1, Applicants respectfully submit that neither the Yoon Patent nor the Koblish Patent disclose all of the elements recited in independent claim 1.

Claims 2, 56 and 57 depend from independent claim 1, and Applicants respectfully assert that these claims are also allowable over the Yoon Patent for at least the same reasons provided with respect to independent claim 1 above.

Claims 58, 59, 62 and 63 depend from independent claim 1, and Applicants respectfully assert that these claims are also allowable over the Koblish Patent for at least the same reasons provided with respect to independent claim 1 above.

Accordingly, Applicants respectfully submit that the subject matter recited in pending claims 1, 2 and 56-67 is not disclosed in either the Yoon Patent or the Koblish Patent, and that the rejections of claims 1, 2, 56-59, 62 and 63 under 35 U.S.C. § 102(b) should be withdrawn.

With respect to the rejection of dependent claim 61 under § 103(a), the Examiner admits that the Koblish Patent does not teach using a shape-memory material as recited in claim 61, but contends that a skilled artisan would be motivated to shape memory materials to achieve a desired shape as the use of these materials is allegedly well known and obvious. (See *Final Office Action*, p. 4, lines 1-5.) However, Applicants respectfully assert that one of ordinary skill in the art at the time the invention was made would not have been motivated to use a wire comprising shape-memory material as recited in claim 61. In particular, as wire strands 70, 72 in the Koblish Patent are used to connect the proximal extensions of jaws 30, 32 to actuation wire 60 (see, e.g. the *Koblish Patent*, Fig. 2 and col. 5, lines 3-19), there would have been no motivation to use wire comprising

shape-memory material, which is believed to be more costly than other suitable wires, and there would be no reason to do that in the Koblish Patent. Accordingly, Applicants respectfully submit that the subject matter claimed in pending claim 61 would not have been obvious to one of ordinary skill in the art at the time the invention was made, and that the rejection of claim 61 under 35 U.S.C. § 103(a) should be withdrawn.

With respect to the rejections of claims 64-67 under § 103(a) as being obvious over the Yoon Patent in view of the Houser Patent or the Tu Publication, the Examiner admittedly relies on the Yoon Patent and then contends that the Houser Patent discloses the additional limitations recited in dependent claims 64-66 and that the Tu Publication discloses the additional limitations recited in dependent claim 67. However, as discussed above with respect to claim 1, Applicants respectfully assert that the Yoon Patent fails to teach, suggest or disclose the subject matter recited in independent claim 1 and the claims which depend therefrom for at least the reasons discussed above. In addition, Applicants respectfully assert that the Houser Patent and the Tu Publication fail to cure the deficiencies of the Yoon Patent to the subject matter recited in independent claim 1 and the claims which depend therefrom. Accordingly, Applicants respectfully submit that the subject matter claimed in pending claims 64-67 is not taught or suggested in any of the cited references, taken alone or in combination, and that the rejection of claims 64-67 under 35 U.S.C. § 103(a) should be withdrawn as well.

IV. NEW CLAIMS

New claims 68 and 69, which depend from independent claim 1, have been added above to cover certain exemplary embodiments of Applicants' invention. Support for these new claims can be found in the originally-filed specification and drawings. Applicants respectfully assert that new claims 68 and 69 are allowable over the Yoon Patent, the Koblish Patent, the Houser Patent and the Tu Publication, either taken alone or in combination. It is respectfully requested that a confirmation of patentability of these claims be provided in the next communication for this application to Applicants' representatives.

V. CONCLUSION

In light of the foregoing, Applicants respectfully submit that pending claims 1, 2 and 56-68 are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited. The Examiner is invited to contact the undersigned to expedite the prosecution of this application if any issues remain outstanding.

Respectfully submitted,

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